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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/084,240 | 02/27/2002 | Raymond R. Rackley | 54459-237216 | 2031 |
| 25764 | 7590 | 11/16/2004 | EXAMINER | |
| FAEGRE & BENSON LLP PATENT DOCKETING 2200 WELLS FARGO CENTER MINNEAPOLIS, MN 55402 | | | THANH, LOAN H | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3763 | |

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

is

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|------------------------------|-------------------------------|--------------------------------|--|
| Office Action Summary | Application No. 10/084,240 | Applicant(s) RACKLEY ET AL. | |
| | Examiner LoAn H. Thanh | Art Unit 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 12-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 12-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>09/01/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The IDS filed 09/01/04 has been considered.

The rejection under 35 USC § 102 (a) has been withdrawn.

The declaration filed on 09/01/04 under 37 CFR 1.131 is sufficient to overcome the Carbon Medical Technologies memo reference.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

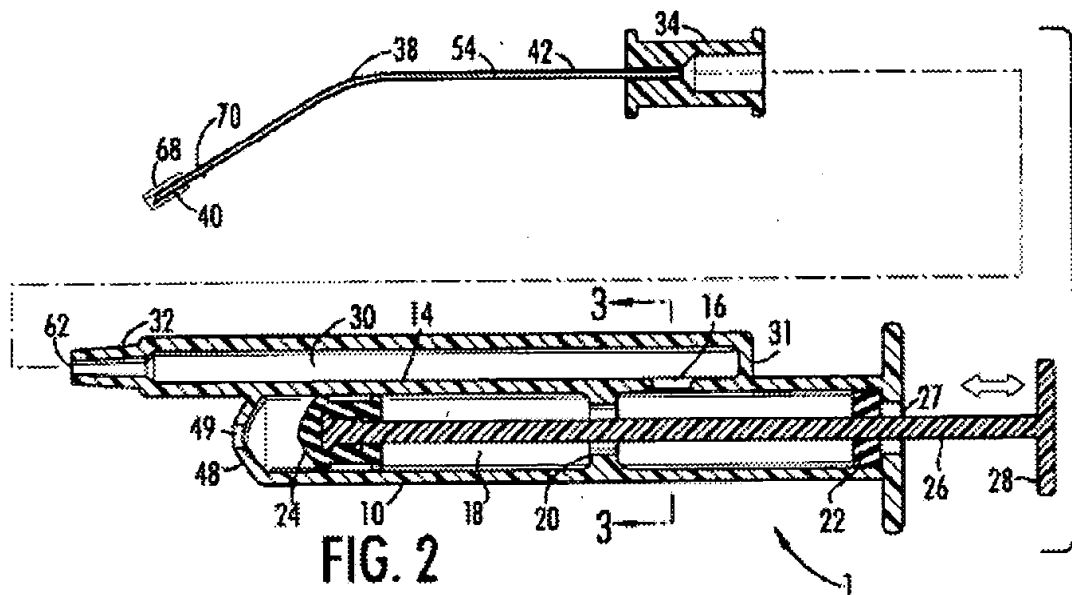
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,5-6,12,15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Hill (U.S. Patent No. 6,258,067).

Hill discloses an apparatus comprising a syringe, a hypodermic needle, and a 5-45 degree bend.



Claims 1-2,5-6,12, 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Crowther (U.S. Patent No. 1,569,174).

Crowther discloses an apparatus comprising a syringe and a needle with a 15 degree bend. See figure 4.

Claims 1,3-6, 12,15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Evans (U.S. Patent No. 4,518,383).

Evans discloses an apparatus comprising a syringe and a needle with a 20 degree bend and needle length of about 1.5- 60 inches or 1.5-5 inches. See figure 1-2, 5-9.

Claims 1-5,12, 15,17 are rejected under 35 U.S.C. 102(e) as being anticipated by Stone (US 6,666,848).

Stone disclose an apparatus comprising a syringe containing a bulking agent and a needle with a bend. See figure 3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,5-7, 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawin et al. (U.S. Patent No. 5,792,478) in view of Hill (U.S. Patent No. 6,258,067) .

Lawin et al. disclose a kit comprising injection of a plurality of discrete coated particles in a carrier having dimensions between 200 and 500 microns. See abstract and columns 2-4. However, Lawin et al. does not disclose a bend needle or a depth shield. Hill discloses a syringe having a bend needle with a depth shield to prevent further penetration of the needle in the analogous art of syringes. It would have been obvious to one of ordinary skill in the art to modify the syringe/ delivery device of Lawin et al. with a bent needle and shield as taught by Hill in order to provide better maneuvering of the needle to the target location and to prevent further penetration of the needle to the desired location.

Response to Arguments

Applicant's arguments filed 09/01/04 have been fully considered but they are not persuasive. Applicant is reminded that the claims are directed to apparatus claims. The device of the prior art is capable of performing the intended use. Lacking any further structural distinguishing feature of a "bulking agent", the devices of the prior art is considered to house/contain a bulking agent.

Conclusion

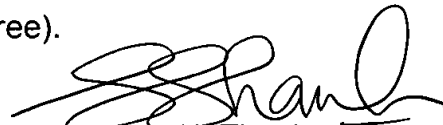
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LoAn H. Thanh
Primary Examiner
Art Unit 3763

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